AMENDMENT TO H.R.

OFFERED BY MR. ALLEN

(Page & line nos. refer to Committee Print of 6/13/03)

Insert at the appropriate place the following:

SEC. ___. CMS RESEARCH AND STUDY ON EFFECTIVENESS OF CERTAIN PRESCRIPTION DRUGS.

(a) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services (in this section referred to as the ''Administrator'')—

(1) shall provide for the conduct of research, which may include clinical research, to develop valid scientific evidence regarding the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition; and

(2) taking into consideration the research conducted under paragraph (1), shall use evidence-based practice centers to conduct studies or other analyses of the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(b) SAFETY.—In any analysis of comparative effectiveness or cost-effectiveness under subsection (a)(2), the Administrator shall include a discussion of available information on relative safety.

(c) STANDARDS.—The Administrator, in consultation with the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and stakeholders, shall develop standards for the design and conduct of cost-effectiveness studies under this subsection.

(d) COVERED PRESCRIPTION DRUGS.—For purposes of this section, the term ''covered prescription drugs'' means prescription drugs that, as determined by the Administrator, account for high levels of expenditures or use by individuals in Medicare.

(e) ANNUAL REPORTS.—Each year the Administrator shall prepare and submit to the Congress a report on the results of the research, studies, and analyses conducted under this section.

(f) REPORTS FOR PRACTITIONERS.—As soon as possible, but not later than a year after the completion of any study under subsection (a)(2), the Administrator shall—

(1) prepare a report on the results of such study for the purpose of informing health care practitioners; and

(2) publish the report on the Internet and through other means that will facilitate access by practitioners.

(g) EVIDENCE.—In carrying out this section, the Administrator shall consider only methodologically sound studies, giving preference to studies for which the Administrator has access to sufficient underlying data and analysis to address any significant concerns about methodology or the reliability of data.

(h) AGREEMENTS.—The Administrator may enter into agreements with the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality to carry out this section.